



BILLING CODE 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2015-0420; FRL-9946-62]

Bacillus amyloliquefaciens strain PTA-4838; Exemption from the Requirement of a Tolerance

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: This regulation establishes an exemption from the requirement of a tolerance for residues of the *Bacillus amyloliquefaciens* strain PTA-4838 on all food commodities when applied or used as a fungicide, nematocide, or plant growth regulator. LidoChem, Inc. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA), requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of *Bacillus amyloliquefaciens* strain PTA-4838.

DATES: This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the

SUPPLEMENTARY INFORMATION).

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2015-0420, is available at <http://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: Robert McNally, Director, Biopesticides and Pollution Prevention Division (7511P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; main telephone number: (703) 305-7090; email address: BPPDFRNotices@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but

rather provides a guide to help readers determine whether this document applies to them.

Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

B. How Can I Get Electronic Access to Other Related Information?

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at http://www.ecfr.gov/cgi-bin/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl.

C. How Can I File an Objection or Hearing Request?

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2015-0420 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before *[insert date 60 days after date of publication in the **Federal Register**]*. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2015-0420, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.
- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.
- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

II. Background and Statutory Findings

In the **Federal Register** of August 26, 2015 ([80] FR 51759) (FRL-9931-74), EPA issued a document pursuant to FFDCA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP [4F8317]) by LidoChem, Inc.,

20 Village Ct., Hazlet, NJ 07730. The petition requested that 40 CFR part 180 be amended by establishing an exemption from the requirement of a tolerance for residues of *Bacillus amyloliquefaciens* strain PTA-4838. That document referenced a summary of the petition prepared by the petitioner LidoChem, Inc., which is available in the docket, <http://www.regulations.gov>. There were no comments received in response to the notice of filing.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is “safe.” Section 408(c)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to FFDCA section 408(c)(2)(B), in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in FFDCA section 408(b)(2)(C), which require EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....” Additionally, FFDCA section 408(b)(2)(D) requires that the Agency consider “available information concerning the cumulative effects of a particular pesticide's residues” and “other substances that have a common mechanism of toxicity.”

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

III. Toxicological Profile

Consistent with FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action and considered its validity, completeness and reliability, and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children.

Bacillus amyloliquefaciens is a gram positive non-pathogenic bacterium which is commonly found in the air, water, soil, and on plants. *Bacillus amyloliquefaciens* is ubiquitous in the environment, especially in soils and agricultural environments all over the world.

Bacillus amyloliquefaciens was previously classified as *Bacillus subtilis* var. *amyloliquefaciens*. (Ref 1). *B. subtilis* var. *amyloliquefaciens* is used to produce proteolytic enzymes for laundry detergents, is used in broiler feed as a probiotic, and produces chitinase, protease, and lipases which suppress fungi and nematodes. It has also been reported as having plant growth regulator activity. *Bacillus subtilis* sp. are known to cause spoilage in dough, and are rarely found to cause food poisoning (Ref. 2).

Between 1990-1996 ten different foods have been associated with *B. subtilis* foodborne illness outbreaks, other infrequent cases have been reported as well (Ref. 3), but no

reported foodborne illnesses have been associated with *Bacillus amyloliquefaciens* or *Bacillus amyloliquefaciens* PTA-4838. *Bacillus amyloliquefaciens* infections have only been associated with amyloisin producing strains and presence of other pathogens isolated from indoor dust in water damaged buildings (Ref. 3), and infections have not been associated with any dietary consumption. The production of amyloisin has not been reported with *Bacillus amyloliquefaciens* PTA-4838 strain, and the acute pulmonary toxicity pathogenicity studies show no signs of toxicity or pathogenicity for this strain. Thus, *Bacillus amyloliquefaciens* PTA-4838 strain is not considered a risk for infection.

Acute oral, pulmonary, and injection toxicity/pathogenicity testing of *Bacillus amyloliquefaciens* strain PTA-4838 has shown that it is not toxic or pathogenic. Specific information on the studies received and other available information concerning potential effects of *Bacillus amyloliquefaciens* strain PTA-4838 can be found at <http://www.regulations.gov> in the document titled “Registration Decision for the New Active Ingredient *Bacillus amyloliquefaciens* strain PTA-4838” in this docket ID number EPA-HQ-OPP-2015-0420. (Ref. 4).

As no adverse effects have been observed in the available data for *Bacillus amyloliquefaciens* strain PTA-4838, the Agency has not identified any points of departure for conducting a quantitative assessment of *Bacillus amyloliquefaciens* strain PTA-4838. Consequently, the Agency conducted a qualitative assessment.

IV. Aggregate Exposures

In examining aggregate exposure, FFDCA section 408 directs EPA to consider available information concerning exposures from the pesticide residue in food and all

other non-occupational exposures, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other indoor uses).

A. Dietary Exposure

1. *Food. Bacillus amyloliquefaciens* is ubiquitous in the environment, especially in soils and agricultural environments, so dietary exposure to background levels of the naturally occurring microbe are already occurring. *B. subtilis* and *B. amyloliquefaciens* are considered GRAS food additives and the FDA has estimated that dietary exposure of *B. subtilis* and *B. amyloliquefaciens* by the U.S. population is 200 mg/day (Ref.5). Similar *Bacillus subtilis* strains are used in the production of food grade products and in fermented foods in Japan and Thailand. Dietary exposure via crop residues from pesticidal uses will be much lower based on maximum application rates. Further, the product containing *Bacillus amyloliquefaciens* PTA-4848 is not toxic or pathogenic and is not expected to cause adverse health effects, and has not been connected to any illnesses.

2. *Drinking water exposure. Bacillus amyloliquefaciens* naturally present in soils; therefore, *Bacillus amyloliquefaciens* may occur in surface water and possibly groundwater. According to the World Health Organization, *Bacillus* species are often detected in drinking water even after going through acceptable water treatment processes, mostly because the spores are resistant to municipal water treatment measures. Should this microbial pesticide be present, no adverse effects are expected from exposure to

Bacillus amyloliquefaciens through drinking water (Ref. 6), based on the results outlined in the Toxicological Profile Section.

B. Other Non-Occupational Exposure

The pesticide use of *Bacillus amyloliquefaciens* PTA-4838 except during application right before harvest, as proposed, does not increase in a significant way the potential for non-dietary, non-occupational exposure to its residues for the general population, including infants and children, because *Bacillus amyloliquefaciens* is ubiquitous in the environment and because populations have been previously exposed to background levels of the microbe. Children are not expected to have any incidental exposure at levels above what they are naturally exposed to already. Human exposure to *Bacillus subtilis* and *Bacillus amyloliquefaciens* in food grade products or fermented foods have not resulted in any reports of infection. As previously mentioned *Bacillus subtilis* and *Bacillus amyloliquefaciens* dietary exposure is reported as 200 mg/per person per day in the U.S. (Ref. 5) Any additional exposure to *Bacillus amyloliquefaciens* PTA-4838 resulting from residues from pesticidal use and residential homeowner applications will not result in additional aggregate non occupational risk, since no acute oral, pulmonary, and injection toxicity or pathogenicity hazard exists.

V. Cumulative Effects from Substances with a Common Mechanism of Toxicity

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

B. amyloliquefaciens strain PTA-4838 does not share a common mechanism of toxicity with any other substances, since it is not toxic via the oral, dermal, or inhalation routes of exposure. For the purposes of this tolerance action, therefore, EPA has assumed that *Bacillus amyloliquefaciens* strain PTA-4838 does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

VI. Determination of Safety for U.S. Population, Infants and Children

A. U.S. Population

Although there is likely to be dietary and non-occupational exposure to *Bacillus amyloliquefaciens* strain PTA-4838, the Agency concludes that there is reasonable certainty that no harm will result to the U.S. population, including infants and children, from aggregate exposure to residues of *Bacillus amyloliquefaciens* strain PTA-4838 because of the lack of any toxicity, infectivity, and pathogenicity of this microbe. This includes all anticipated dietary exposures and all other exposures for which there is reliable information.

B. Infants and Children

FFDCA section 408(b)(2)(C) provides that the EPA shall apply an additional tenfold (10X) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure, unless the EPA determines based on reliable data that a different

margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act Safety Factor. In applying this provision, the EPA either retains the default value of 10X or uses a different additional safety factor when reliable data available to the EPA support the choice of a different factor.

As discussed above, EPA has concluded that *Bacillus amyloliquefaciens* strain PTA-4838 is not toxic, pathogenic, or infective to mammals, including infants and children. Because there are no threshold levels of concern to infants, children, and adults when *Bacillus amyloliquefaciens* strain PTA-4838 is used according to label directions and good agricultural practices, EPA concludes that no additional margin of safety is necessary to protect infants and children.

VII. Analytical Enforcement Methodology

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

VIII. Conclusions

Therefore, an exemption is established for residues of *Bacillus amyloliquefaciens* strain PTA-4838 on all food commodities.

IX. References

1. Priest, F., Goodfellow, M., Shute, L., and Berkeley, R. 1987. "*Bacillus amyloliquefaciens* sp. nom., nom. rev." *International Journal of Systematic Bacteriology*. 37: 69-71. <http://ijs.sgmjournals.org/content/37/1/69.full.pdf>.

2. https://microbewiki.kenyon.edu/index.php/Bacillus_subtilis.
3. Apetroaie-Constantin, C., et al. (2009). "*Bacillus subtilis* and *B. mojavensis* strains connected to food poisoning produce the heat stable toxin amyloisin." *Journal of applied microbiology* 106 (6): 1976-1985.
4. Registration Decision for the New Active Ingredient *Bacillus amyloliquefaciens* strain PTA-4838, <http://www.regulations.gov>. Docket No. EPA-HQ-OPP-2015-0420.
5. <http://www.fda.gov/ohrms/dockets/98fr/042399a.txt>.
6. <https://www.gpo.gov/fdsys/pkg/FR-2012-01-06/pdf/2011-33846.pdf>, **Federal Register** (77 FR 745, January 6, 2012).

X. Statutory and Executive Order Reviews

This action establishes an exemption from the requirement of a tolerance under FFDCA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled "Regulatory Planning and Review" (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled "Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use" (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled "Protection of Children from Environmental Health Risks and Safety Risks" (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the

Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the exemption in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000) do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

XI. Congressional Review Act

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of the rule in the **Federal Register**. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 180

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: June 1, 2016.

Jack E. Housenger,

Director, Office of Pesticide Programs.

Therefore, 40 CFR chapter I is amended as follows:

PART 180--[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1336 is added to subpart D to read as follows:

§180.1336 *Bacillus amyloliquefaciens* strain PTA-4838; exemption from the requirement of a tolerance.

An exemption from the requirement of a tolerance is established for residues of *Bacillus amyloliquefaciens* strain PTA-4838 in or on all food commodities.